OXYTOCIN

Solution for Injection

DATA SHEET

INDICATIONS

Uterine inertia, retention of the placenta, agalactia, prevention of haemorrhages after caesarean section or after hard delivery in horses, cattle, sheep, goats, pigs, dogs and cats.

BENEFITS

- For use in multiple species
- Zero milk and meat withdrawal
- Options for intramuscular or intravenous administration in the mare, bitch or queen. Intramuscular administration in the cow, ewe, nanny or sow.

LIST No	UNIT PACKAGE	CASE SIZE
1OXY037	50 ml	12

See reverse for Administration & Dosage

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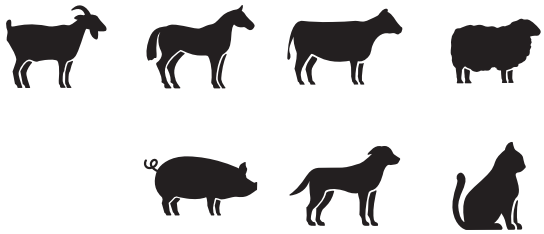

ACTIVE SUBSTANCE
Oxytocin (synthetic) 10 I.U. per ml. Solution for injection. A clear, colourless solution.

TARGET SPECIES
Horses, cattle, sheep, goats, pigs, dogs and cats.

INDICATIONS FOR USE
Uterine inertia, retention of the placenta, agalactia, prevention of haemorrhages after caesarean section or after hard delivery.

AMOUNTS TO BE ADMINISTERED AND ADMINISTRATION ROUTE
For intramuscular or intravenous injection.

Obstetrics:
Mare: 20-50 IU per animal by intramuscular injection. 40-50 IU per animal by slow intravenous infusion (over 1 hr).
Cow: 20-50 IU per animal by intramuscular injection.
Ewe: 5-30 IU per animal by intramuscular injection.
Goat: 5-15 IU per animal by intramuscular injection.
Sow: 10-40 IU per animal by intramuscular injection.
Bitch: 0.5-3 IU per animal depending on bodyweight by intramuscular injection (administration during delivery). 0.3-2 IU intravenous or 1-10 IU by intramuscular injection (administration post-partum).
Queen: 0.3-1 IU per animal depending on bodyweight by intramuscular injection (administration during delivery). 0.15-1 IU intravenous or 1-3 IU by intramuscular injection (administration post-partum).

During or shortly after delivery the minimum dose should be administered in all large animal species; this dosage can be repeated after approximately 30 minutes. The maximum dosage should be administered when several hours have passed since delivery.

Milk let down:
Cow and mare: 10-40 IU
Ewe, goat and sow: 5-20 IU
Bitch and queen: 1-10 IU

WITHDRAWAL PERIOD(S)
Meat and offal: Zero days
Milk: Zero hours

CONTRAINDICATIONS
Do not use in cases of incomplete dilation of the cervix or any form of obstructive dystocia. Do not use in cases of hypersensitivity to the active substance or any of the excipients.

SPECIAL WARNINGS
When oxytocin is used as an aid to parturition, cervical dilation must be confirmed prior to administration to prevent the risk of foetal death and possible uterine rupture.
Adrenaline at physiological levels markedly reduces the effect of oxytocin on the uterus or mammary gland. For this reason the animal should not be frightened when complete oxytocin effect is desired to cause either milk "let down" or uterine contractions.

SPECIAL PRECAUTIONS FOR USE IN ANIMALS
If uterine hyperactivity occurs, oxytocin administration should be discontinued immediately. Oxytocin should not be given simultaneously by more than one route of administration.

SPECIAL PRECAUTIONS TO BE TAKEN BY THE PERSON ADMINISTERING THE VETERINARY MEDICINAL PRODUCT TO ANIMALS
Hypersensitivity reactions may rarely occur; avoid skin contact with the solution.

ADVERSE REACTIONS
Hypersensitivity reactions sometimes occur.

USE DURING PREGNANCY OR LACTATION
Do not use during pregnancy. Only when the animal is full term should the product be administered.

INTERACTION WITH OTHER MEDICINAL PRODUCTS
Severe hypertension has been reported in humans when oxytocin was given 3-4 hours following prophylactic administration of a vasoconstrictor in conjunction with caudal block anaesthesia. Reports of interactions in the veterinary science are lacking.

OVERDOSE
When oxytocin is administered in excessive dosage, hyperstimulation of the uterus, with strong (hypertonic) and/or prolonged (tetanic) contractions, or an increased uterine tone between the contractions may occur, possibly resulting in uterine rupture, cervical and vaginal lacerations, postpartum haemorrhage, placental separation, impaired uterine blood flow, amniotic fluid embolism and foetal trauma including intracranial haemorrhage. Excessive doses of oxytocin may delay parturition by producing uncoordinated uterine contractions which interfere with the progress of the foetus especially in multiple pregnancies.

PHARMACODYNAMIC PROPERTIES
Oxytocin is a naturally occurring hormone present in the female and male organism of all mammalian species. Its chemical structure is a nonapeptide.
Oxytocin causes marked contraction of smooth muscle, in particular the uterus and the myoepithelial cells surrounding the milk secreting alveolus of the mammary gland. Functionally, oxytocin has a role in parturition and milk ejection. Oxytocin changes the weak spontaneous and irregular contractions of the oestrogen stimulated uterus into regular forceful and purposeful contractions. On the lactating mammary gland oxytocin provokes contractions of the myoepithelial tissue thus causing milk-ejection and at suckling stimulus milk let-down. Shortly before, during and shortly after birth susceptibility to the effects of oxytocin is distinct, but this susceptibility declines in time, and 24 hours after delivery dosages should be significantly increased.

PHARMACOKINETIC PARTICULARS
The distribution and fate of oxytocin in the body following injection is characterized by a fast absorption and a short half-life in plasma and a rapid removal from plasma by kidney and liver. The lactating mammary gland inactivates a significant portion of the circulating hormone. Excretion is mainly renal.

MAJOR INCOMPATIBILITIES
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

SHELF-LIFE
Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

SPECIAL PRECAUTIONS FOR STORAGE
Store in a refrigerator (2°C - 8°C). Do not freeze.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

MARKETING AUTHORISATION HOLDER
Eurovet Animal Health B.V.
Handelsweg 25,
5531 AE Bladel,
Netherlands,

DISTRIBUTED IN IRELAND BY
Bimeda Animal Health Ltd,
Unit 2,3,4 Airton Close,
Airton Road,
Tallaght,
Dublin 24
D24 FH9V
Tel: +353 (0) 1466 7900

MARKETING AUTHORISATION NUMBER
VPA10989/044/001

LEGAL STATUS
POM
Prescription Only Medicine as defined in relevant national legislation

SPC
To view the full product SPC, visit the HPRA website
Use Medicines Responsibly

TAKE TIME OBSERVE LABEL DIRECTIONS

www.bimeda.ie

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